No. 87-1194

IN THE
Supreme Court of the United States
OCTOBER TERM, 1987

THE COSMETIC, TOILETRY AND FRAGRANCE ASSOCIATION,
Petitioner,

v.

PUBLIC CITIZEN, *et al.*,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

REPLY BRIEF FOR PETITIONER

PETER BARTON HUTT *
ELLEN J. FLANNERY
BRUCE N. KUHLIK
COVINGTON & BURLING
1201 Pennsylvania Ave., N.W.
P.O. Box 7566
Washington, D.C. 20044
(202) 662-6000
Attorneys for Petitioner

* Counsel of Record

TABLE OF AUTHORITIES

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Far from supporting a denial of CTFA's petition, the government's brief underscores the need for review by this Court. The government admits that the color additive Delaney Clause was "patterned after" the food additive Delaney Clause (Br. in Opp. 2); that the decisions of the lower courts now "lead to anomalous results" (*id.* at 6-7 & n.7); and that it is "troubled by some of [the] implications" of the decision below (*id.* at 5). Despite these factors strongly

favoring review, the government urges that the decision invalidating FDA's *de minimis* policy go unreviewed because the case does not involve a food additive, there is no square conflict in the circuits, and the views of FDA—which has already issued several final rules relying on the *de minimis* policy—are allegedly "still undergoing refinement" (*id.* at 9). The weakness of the government's opposition is apparent from its own brief.[1]

1. Although it acknowledged in the court of appeals (Gov't C.A. Br. 18) that the color additive Delaney Clause is "identical to [the] one enacted for food additives in 1958," the government now merely

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[1] Public Citizen's opposition primarily argues the merits and defers to the government on the importance of the decision. Nowhere, however, does Public Citizen explain how a statutory provision intended to protect humans, not laboratory animals, is served by banning substances that present no risk of cancer to humans. Moreover, Public Citizen's extensive reliance on the language of the Delaney Clause ignores the fact that the basis for the *de minimis* doctrine is the agency's *inherent* authority (Pet. 14-15). Its attempt to discount the deference due the agency because FDA's policy has changed over time ignores both the agency's authority to engage in reasoned modification of its course as well as the evolutionary nature of FDA's interpretation of the Delaney Clause in light of developing scientific knowledge (Pet. 20-22). Finally, Public Citizen's reliance on R. Merrill & P. Hutt, *Food and Drug Law* (1980) is misplaced. That source acknowledges (*id.* at 78) that "the Delaney Clause leaves the FDA room for scientific judgment in deciding whether its conditions are met," and it quotes (*id.* at 80) an article concluding that the Delaney Clause " 'is utterly irrelevant to current food safety policy' " because it merely duplicates FDA's standards under the general safety clauses of the statute (quoting Hutt, *Public Policy Issues in Regulating Carcinogens in Food,* 33 Food Drug Cosm. L.J. 541 (1978)).

points out (Br. in Opp. 7-8) that the lower court ignored the 1958 legislative history—which was the fundamental error of the court of appeals (*see* Pet. 15-18). Congress expressly stated that the 1960 provision was "similar" to the 1958 clause, and it based the color additive provision on the same considerations "that gave rise to the Delaney anticancer clause in the Food Additives Amendment." H.R. Rep. No. 1761, 86th Cong., 2d Sess. 11 (1960). The 1958 legislative history is thus demonstrably relevant to the 1960 provision, a premise confirmed by this Court's precedents (cited at Pet. 16).

The government responds (Br. in Opp. 7) that the lower court ignored the 1958 legislative history because the "context" was different for food additives. The basis for this suggestion apparently is that food additives have greater social value than color additives (*see id.* at 7-8 n.8). This argument fails for three reasons. First, there is no suggestion in the 1960 legislative history that Congress intended to apply a different interpretation to the color additive Delaney Clause than it intended for the food additive provision. Second, there is likewise no indication that Congress intended any sort of cost-benefit principle to apply under the Delaney Clause, granting the agency greater discretion to approve more valuable additives. Finally, even if such a principle were applicable, Congress recognized that use of color additives is "in the consumer's interest and affirmatively desired by consumers" and that an inflexible ban would place industry "in a serious situation." S. Rep. No. 795, 86th Cong., 1st Sess. 11 (1959). Thus, Congress concluded (*id.*):

> There is no justification, from the point of view of the public interest, in driving either color manufacturers or food, drug, or cosmetic pro-

> ducers, dependent upon the use of color, out of business where the particular use of color involved is one which can safely be admitted . . . .

Since the color additives involved here can safely be used under their approved conditions, Congress did not intend to foreclose FDA from permitting such use. *See* Br. in Opp. 3 ("there is no discernible threat to human safety from their use").

2. While it notes (Br. in Opp. 5, 7 n.6) some of the troubling implications of the court of appeals' decision,[2] the government relies (*id.* at 3-4) on the lower court's mistaken distinction between food additives and color additives in arguing that the decision below lacks sufficient importance to warrant review. The government states (*id.* at 8) that the decision below "leaves open the possibility that [the court] will uphold a decision by the FDA finding that a food additive that entails a de minimis risk of cancer to man is not subject to the Delaney Clause . . . ." The government refuses to acknowledge, however, that such a distinction between food additives and color additives would conflict with current FDA policy.

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[2] The government agrees with CTFA and the court of appeals that invalidation of the *de minimis* policy "would actually increase the risks to the public health" (Br. in Opp. 7 n.6). In addition, without a *de minimis* policy, the Delaney Clause would force FDA to allocate an unreasonable share of its resources to questions of speculative carcinogenicity rather than on the basis of actual human safety concerns. Applying the *de minimis* policy would still lead to vigorous agency action against human carcinogens under the general safety clauses; the only difference is that FDA would not waste resources pursuing substances that pose essentially no risk of human cancer.

FDA has never before suggested that it would apply the Delaney Clause any differently to food additives than to color additives. In fact, the agency has relied on prior judicial interpretation of the color additive Delaney Clause as support for decisions under the food additive Delaney Clause.[3] There is no basis for concluding that FDA would now construe the clauses differently, applying the *de minimis* doctrine under one when it has been invalidated under the other. FDA's belief that the decision below requires identical treatment of the clauses is confirmed by the statement of an FDA official quoted in our petition (at 30 n.44), which the government's opposition neither disputes nor retracts.[4]

Industry must therefore anticipate that the food additive Delaney Clause may be applied to ban numerous substances throughout the food supply that present insignificant risks of human cancer. *See* Pet. 24-25. This prospect could lead to costly product modifications and restriction of consumer choice as products become unavailable. A final judicial interpretation should be made now, rather than forcing

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[3] For example the agency's "constituents policy," which was approved in Scott v. FDA, 728 F.2d 322 (6th Cir. 1984) (per curiam), in the particular context of a color additive case, has been relied on by FDA to approve food additives. *See, e.g.*, 50 Fed. Reg. 49684, 49685 (1985); 50 Fed. Reg. 36872, 36873 (1985); 50 Fed. Reg. 4643, 4644 (1985); 49 Fed. Reg. 13021, 13022 (1984); 49 Fed. Reg. 13018, 13019 (1984).

[4] Although the government mentions (Br. in Opp. 8) that there is an exception to the definition of "food additive" for substances that are generally recognized as safe, it does not dispute the statement in our petition (at 25) that application of this exception to animal carcinogens would conflict with past FDA practice.

industry members to expose themselves to lawsuits and charges of illegality in order to obtain a further, probably futile test of the *de minimis* policy discredited by the court of appeals.[5]

3. The government acknowledges (Br. in Opp. 6-7) that the lower court cases cannot be reconciled on any principled basis, since they "lead to anomalous results when considered along with the ruling in this case."[6] In addition, the government points out (*id.* at 7 n.7) that a square conflict should not be required for review in this Court because all FDA decisions are reviewable in the District of Columbia Circuit and thus a conflict might never arise. Finally, the government does not dispute the statement in our petition (at 29-30) that FDA has never persisted in an interpretation invalidated by one court of appeals in the hope of generating a circuit conflict.[7] These

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[5] The risks to industry are heightened by the government's studied refusal in its brief to state expressly that it endorses the *de minimis* doctrine or that the court of appeals erred by invalidating it.

[6] For example, the court of appeals in *Scott* v. *FDA*, *supra*, upheld FDA's approval of a color additive with a cancer risk to humans several orders of magnitude greater than the risk from D&C Orange No. 17, which the court of appeals here held could not be approved.

[7] The government notes (Br. in Opp. 7 n.7) that another challenge to color additive approvals under the *de minimis* policy is pending in the Third Circuit. It is telling, however, that the government has not represented to the Court whether FDA will or will not continue to litigate that case under the *de minimis* theory if review is denied here. Thus, the Court has no basis for denying the petition on the ground that it can be assured of an opportunity to revisit the question following consideration by another court of appeals.

factors strongly counsel in factor of review in this case.

4. The government nonetheless argues (Br. in Opp. 9) against review on the surprising ground that "the government's views are still undergoing refinement." There is no factual support for this assertion. FDA's rules approving the color additives in issue here were final regulations of the agency, and they have been followed by final rules invoking the *de minimis* policy to approve other color additives as well. Contrary to the government's assertion (*id.*) that it has "only recently begun to consider the appropriate role of quantitative risk analysis in applying the Delaney Clause," FDA has been considering this scientific method and applying it to substances under both the Delaney Clause and the general safety clause for 15 years. *See, e.g.*, sources cited at Pet. 21 n.31. The approvals at issue here thus are the product of the agency's deliberate consideration of a difficult area. There is no basis for the government's suggestion that these final rules are somehow not ripe for review (an argument never made below).

Nor does the government point to any expected development that would change FDA's *de minimis* policy. To the contrary, the decision below will effectively foreclose any such development by making the policy illegal. Similarly, the decision below has forced the Environmental Protection Agency to reconsider whether it can apply a negligible-risk standard to pesticides under the Delaney Clause, which had been recommended by the National Academy of Sciences.[8]

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[8] *See Chemical Regulation Reporter* (BNA) 1330 (Nov. 20, 1987); National Research Council, *Regulating Pesticides in Food: The Delaney Paradox* (1987).

The decision below thus has broad implications for future decisions by federal regulatory agencies.

In summary, if FDA and other agencies change their policies to comply with the decision below, review of the *de minimis* policy will be available only in this case. If, on the other hand, the agencies adhere to the policy, it is vulnerable to attack in the D.C. Circuit, with serious consequences both for the agencies and for regulated industries. Under either approach—and the government does not make clear which it will adopt—review of the decision below is appropriate.

For the foregoing reasons and those stated in the petition, the petition for a writ of certiorari should be granted.

Respectfully submitted,

PETER BARTON HUTT *
ELLEN J. FLANNERY
BRUCE N. KUHLIK
COVINGTON & BURLING
1201 Pennsylvania Ave., N.W.
P.O. Box 7566
Washington, D.C. 20044
(202) 662-6000
Attorneys for Petitioner

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* Counsel of Record